REMARKS

Entry of the amendments is respectfully requested. Claims 1-20 have been amended. Claims 21-23 have been canceled. Applicants reserve the right to file a divisional application on non-elected claims 21-23. Claims 1-20 are pending in the application. Favorable reconsideration and allowance of this application is respectfully requested in light of the foregoing amendments and the remarks that follow.

1. Claim Objections

The Examiner has objected to claims 2-20 because of their use of "A" instead of "The" in the preamble. Claims 2-20 have been amended to replace "A" instead of "The."

Claim 19 is objected to because "ddl" should be "ddI." Claim 19 has been so amended. These amendments in no way are believed to narrow the scope of the claims and are for clarification purposes only. In light of the amendments, withdrawal of this objection is requested.

2. Rejection Under §112, First Paragraph

Claims 1-20 stand rejected under 35 U.S.C. §112, ¶1 as failing to comply with the written description requirement. Claim 1 has been amended to clarify that the ligand is capable of binding to a HLA-DR protein. Claim 1 has also been amended to recite only the components of the formulation, without the intended use. Amended claim 1 is therefore supported by the disclosure. *See, e.g.,* specification of WO00/66173 at Substitute Sheet 2, lines 31-34. HLA-DR is not a HLA **class I** protein, as is stated throughout the Office Action. HLA-DR is a HLA **class II** protein. *See, e.g.,* specification of WO00/66173 at Substitute Sheet 5, lines 29-31. A restricted number of cells are known to express HLA-DR proteins at their surface, which renders the formulation specific towards its targets (e.g., viruses such as HIV and SIV, and cells like activated T cells, macrophages, dendritic cells and B lymphocytes, for example). Many other ligands may be added (see claim 10, for example) to obtain a formulation even more tailored to the phenotype(s) of the targeted cells or viruses. The addition of these additional ligands can be conducted according to the techniques known in the art and as exemplified in pages 12 and 13 of the disclosure (WO00/66173).

In light of the amendment to claim 1 and the foregoing arguments, withdrawal of this rejection is requested.

3. Rejection Under §112, Second Paragraph

Claim 10 stands rejected under 35 U.S.C. §112, ¶2 as being indefinite because of an improper Markush grouping. Claim 10 has been amended to delete the Markush grouping and to recite a ligand further comprising a ligand to proteins such as, *inter alia*, a histocompatibility complex protein other than HLA-DR. Accordingly, claim 10 is definite, and withdrawal of this rejection is requested.

4. Rejection Based Under § 102(b)

i. Rejection of Claims 1-2, 10, 11, 13, and 17

Claims 1-2, 10, 11, 13, and 17 stand rejected under § 102(b) as being anticipated by Phillips et al. (J Immunol 152(6):3168-74, March 1994). The Applicants respectfully traverse this rejection because, as is discussed below, Phillips et al. does not disclose each and every element of the amended claims. Therefore, reconsideration is in order and is respectfully requested.

Claim 1 has been amended to recite "a formulation comprising a ligand capable of binding to a HLA-DR protein, said ligand being coupled to a lipid-comprising vesicle." Phillips et al. does not describe such a formulation. Instead, Phillips et al. teaches that immunoliposomes possessing surface-bound IgG or $F(ab)_2$ specific for CD4 bound to PBMCs from normal, nonimmune mice. (Phillips et al., page 3172, col. 1). Therefore, Phillips et al. does not anticipate amended claim 1 and the claims that depend therefrom. Withdrawal of the rejection of claims 1-2, 10, 11, 13, and 17 based on Phillips et al. is respectfully requested.

ii. Rejection of Claims 1-2, 10-11, 13, and 17

Claims 1-2, 10-11, 13, and 17 stand rejected under § 102(b) as being anticipated by WO 96/10585. The Applicants respectfully traverse this rejection because, as is discussed below, WO 96/10585 does not disclose each and every element of the amended claims. Therefore, reconsideration is in order and is respectfully requested.

WO 96/10585 teaches glycosylated protein-liposome compositions that include an oxidized glycosylated protein and a liposome. WO 96/10585 specifically lists the following: IgG, anti-CD4, anti-CD8, anti-ICAM-1, anti-ICAM-2, CC49, α-Erb-B2, α-CEA, and pancarcinoma antibodies, as well as proteins such as avidin. However, WO 96/10585 does not describe a formulation comprising a ligand to a HLA-DR protein, which is required by amended claim 1 and the claims that depend therefrom. Therefore, WO 96/10585 does not anticipate the claimed subject matter. Withdrawal of the rejection of claims 1-2, 10, 11, 13, and 17 based on WO 96/10585 is respectfully requested.

5. Rejection of Claims 1-9, 14, and 18-20 Under § 103

The rejection of Claims 1-9, 14, and 18-20 as unpatentable over U.S. Patent No. 5,773,027 to Bergeron in view of Zelphati et al. (Antisense Res. Dev. 3(4):323-38, 1998) is respectfully traversed, because, *inter alia*, there is no teaching or suggestion to combine or modify the references to produce the invention of amended claim 1. MPEP §2143.01. Furthermore, even if the references were combined, the invention of amended claim 1 would not result.

The '027 patent teaches liposomes for the treatment of viral diseases and more particularly for the treatment of infections caused by viruses like human immunodeficiency virus (HIV) and cytomegalovirus (CMV). (Abstract). The '027 patent fails to teach or suggest anything about a ligand capable of binding to a HLA-DR protein, as amended claim 1 requires.

Zelphati teaches that antisense oligonucleotides offer the potential to inhibit viral gene expression selectively, although stability and transport into cells limit their efficacy. Zelphati compares the effects of antisense phosphodiester or phosphorothioate oligonucleotides with specificity for *rev* and *tat* genes of HIV-1, either free in solution or encapsulated in immunoliposomes to determine whether encapsulation might circumvent these problems (at page 332). Zelphati found that when encapsulated in immunoliposomes targeted to **class I** molecules, in contrast to their lack of activity in free solution, antisense phophodiester oligonucleotides inhibited viral replication in acutely infected cells and that this inhibition was sequence specific. (page 334). However, Zelphati, alone or in combination with the '027 patent, fails to teach or suggest a formulation comprising a ligand capable of binding to a HLA-DR

protein, which is a **class II** protein, and coupled to a lipid-comprising vesicle as amended claim 1 requires. The results obtained by Zelphati with immunoliposomes targeted to **class I** molecules cannot be taken as predictive of a lipid-comprising vesicle coupled to a ligand capable of binding to a HLA-DR protein as presently claimed. Zelphati et al. teachings therefore do not cure the deficiencies in the teachings of the '027 patent.

In light of the foregoing arguments, withdrawal of the rejection of claims 1-9, 14, and 18-20 is respectfully requested.

CONCLUSION

Extension of Term. The proceedings herein are for a patent application, and the provisions of 37 CFR § 1.136 apply. Applicant believes that a one-month extension of term is required. Accordingly, please consider this a petition therefor, and charge the required fee to Deposit Account No. 23-2053. If any additional extension of term is required, please consider this a petition therefor, and charge the required fee to our account.

It is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,

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